

**REMARKS**

Claims 34 and 35 are added, and therefore claims 14 to 17, 34 and 35 are currently pending and being considered in the present application (*since claims 18 to 33 were previously withdrawn in response to a restriction requirement*).

In view of this response, it is respectfully submitted that all of the presently pending and considered claims are allowable, and reconsideration is respectfully requested.

With respect to paragraph five (5) of the Office Action, the drawings were objected to under 37 C.F.R. § 1.83(a).

The drawings objection is traversed. As regards the objection to the drawings, while 37 C.F.R. § 1.83(a) requires the drawings to show every feature specified in the claims, it also provides that “conventional features disclosed in the description and claims, where their detailed illustration is not essential for a proper understanding of the invention, should be” -- but are not required to be -- “illustrated in the drawing in the form of a graphical drawing symbol or a labeled representation.” The feature of a spring element need not be illustrated since a detailed illustration thereof is not essential for a proper understanding of the claimed subject matter. It is respectfully submitted that those of ordinary skill in the art would properly understand the above features disclosed in the description and the claims, without need for further illustration.

In view of all of the foregoing, withdrawal of the objection to the drawings is respectfully requested.

With respect to paragraph six (6) of the Office Action, claims 14 to 16 were rejected under 35 U.S.C. § 101 as directed to non-statutory subject matter.

The Office Action conclusorily asserts that “[c]laim 14 appears to encompass two statutory classes of invention. While the preamble of [sic] is directed to an apparatus, the body of the claim appears to be directed to a manufacturing process . . . . The claim recites a configuration of the valve housing and connecting piece before the crimp and a configuration of the valve housing and connecting piece after the crimp.” (Office Action, pp. 3 to 4).

While the rejections may not be agreed with, to facilitate matters, claim 14 has been rewritten herein without prejudice to specifically provide that “the valve housing being configured to be joined to the connecting piece”, “the valve housing . . . is configured to be crimped into the at least one notch”, and “the valve housing includes a material bulge having

an average axial distance  $d$  with respect to the notch at a circumference of the connecting piece, the material bulge configured to be shifted inwards in a radial direction and all the way into the notch to generate an axial stress between the valve housing and the inserted connecting piece.” Thus, claim 14 has been rewritten herein without prejudice to recite an apparatus claiming a configuration of the valve housing and connecting piece before the crimp.

Accordingly, it is respectfully submitted that claim 14, as presented, is directed to statutory subject matter, so that claim 14 is allowable. Claims 15 to 16 depend from claim 14, as presented, and are therefore allowable for at least the same reasons as claim 14, as presented.

Withdrawal of the rejections of these claims is therefore respectfully requested.

With respect to paragraph eight (8) of the Office Action, claims 14 to 17 were rejected under the first paragraph of 35 U.S.C. § 112, as to the enablement requirement.

While the rejections may not be agreed with, to facilitate matters, claims 14 and 17 have been rewritten herein without prejudice to provide that “the valve housing includes a material bulge.” Support for these amendments may be found in the Specification, e.g., at page 6, lines 29 to 31; and Figure 2. Therefore, the enablement rejection is plainly obviated by the foregoing.

Accordingly, it is respectfully submitted that claims 14 and 17, as presented, meet the enablement requirement, so that claims 14 and 17 are allowable. Claims 15 to 16 depend from claim 14, as presented, and are therefore allowable for at least the same reasons as claim 14, as presented.

Approval and entry are respectfully requested, as is withdrawal of the enablement rejection.

Also in this regard, the Office Action's assertions and arguments presented simply do not reflect the standard for determining whether a patent application complies with the enablement requirement that the specification describe how to make and use the invention — which is defined by the claims. (See M.P.E.P. § 2164). The Supreme Court established the appropriate standard as whether any experimentation for practicing the invention was undue or unreasonable. (See M.P.E.P. § 2164.01 (citing Mineral Separation v. Hyde, 242 U.S. 261, 270 (1916); In re Wands, 858 F.2d. 731, 737, 8 U.S.P.Q.2d 1400, 1404 (Fed Cir. 1988))). Thus, the enablement test is “whether one reasonably skilled in the art could make or use the

invention from the disclosures in the patent coupled with information known in the art without undue experimentation.” (See id. (citing United States v. Teletronics, Inc., 857 F.2d 778, 785, 8 U.S.P.Q.2d 1217, 1223 (Fed. Cir. 1988))).

The Federal Circuit has made clear that there are many factors to be considered in determining whether a specification satisfies the enablement requirement, and that these factors include but are not limited to the following: the breadth of the claims; the nature of the invention; the state of the prior art; the level of ordinary skill; the level of predictability in the art; the amount of direction provided by the inventor; the existence of working examples; and the quantity of experimentation needed to make or use the invention based on the disclosure. (See id. (citing In re Wands, 858 F.2d at 737, 8 U.S.P.Q.2d at 1404 and 1407)). In this regard, the Federal Circuit has also stated that it is “improper to conclude that a disclosure is not enabling based on an analysis of only one of the above factors,” and that the Office's analysis must therefore “consider all the evidence related to each of these factors” so that any nonenablement conclusion “must be based on the evidence as a whole.” (See M.P.E.P. § 2164.01).

Also, the Office bears the initial burden of establishing why the “scope of protection provided by a claim is not adequately enabled by the disclosure.” (See id. (citing In re Wright, 999 F.2d 1557, 1562, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993))). Accordingly, a specification that teaches the manner and process of making and using an invention in terms that correspond in scope to those used in describing and defining the claimed subject matter complies with the enablement requirement. (See id.).

In contrast to the above, however, the Office Action's unsupported assertions simply do not concern — as they must under the law — whether the present application enables a person having ordinary skill in the art to practice the claimed subject matter of the claims without undue experimentation — which it plainly does, as evidenced, for example, by the above reference to the present application. In short, the Office Action's assertions are merely conclusory and do not address the issue of whether one having ordinary skill would have to unduly experiment to practice the claimed subject matter of the rejected claims — a proposition for which the Office bears the burden of proving a prima facie case as to the rejected claims.

In this regard, to properly establish enablement or non-enablement, the Office must make use of proper evidence, sound scientific reasoning and the established law. In the case of Ex Parte Reese, 40 U.S.P.Q.2d 1221 (Bd. Pat. App. & Int. 1996), a patent examiner

rejected (under the first paragraph of section 112) application claims because they were based on an assertedly non-enabling disclosure, and was promptly reversed because the rejection was based only on the examiner's subjective belief that the specification was not enabling as to the claims. In particular, the examiner's subjective belief was simply not supported by any "evidence or sound scientific reasoning" and therefore ignored recent case law — which makes plain that an examiner (and not an applicant) bears the burden of persuasion on an enablement rejection.

More particularly, the examiner in Ex parte Reese was reversed because the rejection had only been based on a conclusory statement that the specification did not contain a sufficiently explicit disclosure to enable a person to practice the claimed invention without exercising undue experimentation — which the Board found to be merely a conclusory statement that only reflected the subjective and unsupported beliefs of a particular examiner and that was not supported by any proper evidence, facts or scientific reasoning. (See id.). Moreover, the Board made clear that it is "incumbent upon the Patent Office . . . to back up assertions of its own with acceptable evidence," and also made clear that "[where an] examiner's 'Response to Argument' is not supported by evidence, facts or sound scientific reasoning, [then an] examiner has not established a *prima facie* case of lack of enablement under 35 U.S.C. § 112, first paragraph." (See id. at 1222 & 1223; italics in original). In the present case, the Office Action has not even alleged in a conclusory way that undue experimentation would be required. Moreover, even as to the assertions as presented, the present application plainly discloses how to use the subject matter of the rejected claims, as discussed above.

In view of all of the foregoing, it is plain that the Office Action's assertions as to the claim rejections simply do not satisfy the judicial standards discussed above as to the enablement requirement since the arguments and assertions presented do not relate the scope of the claim to the specification to determine whether the specification is enabling, nor do they properly address the enablement factors. It is therefore respectfully submitted that the Office Action has not even established a prima facie case as to the enablement requirement. It is therefore respectfully requested that the enablement rejection be withdrawn based on the foregoing.

With respect to paragraph nine (9) of the Office Action, claims 14 to 17 were rejected under the second paragraph of 35 U.S.C. § 112, as to the definiteness requirement.

As explained above and while the rejections may not be agreed with, to facilitate matters, claims 14 and 17 have been rewritten to better clarify the claimed subject matter, and to replace the term “the inserted connecting piece” with the term --the connecting piece--, thereby obviating the present rejection. It is respectfully submitted that the claims, as presented, comply with the definiteness requirement of the second paragraph of 35 U.S.C. § 112.

Accordingly, it is respectfully submitted that claims 14 and 17, as presented, meet the definiteness requirement, so that claims 14 and 17 are allowable. Claims 15 to 16 depend from claim 14, as presented, and are therefore allowable for at least the same reasons as claim 14, as presented.

Approval and entry are respectfully requested, as is withdrawal of the indefiniteness rejections.

New claims 34 and 35 do not add any new matter and are supported by the present application, including the specification. Claims 34 and 35 respectively depend from claims 14 and 17, and are therefore allowable for the same reasons as their respective base claims.

Withdrawal of the rejections of the pending and considered claims is therefore respectfully requested.

**CONCLUSION**

It is therefore respectfully submitted that all of the presently pending and considered claims 14 to 17, 34 and 35 are allowable. It is therefore respectfully requested that the rejections (and any objections) be withdrawn, since all issues raised have been addressed and obviated. An early and favorable action on the merits is therefore respectfully requested.

Respectfully submitted,

Dated: 3/25/08

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